

### **Remarks**

Claims 1-15 were pending in this application. By this Amendment, claims 1-5 and 7-15 are canceled without prejudice to prosecution in another application. Claim 6 is amended. Support for this amendment can be found throughout the specification, including at least at page 9, paragraph 0032 and page 26, paragraph 0074 to page 27, paragraph 0076. New claims 16-18 are added. Support for the new claims can be found throughout the specification, including at least at page 3, paragraph 009 and page 7, paragraph 0025.

No new matter is introduced by the foregoing amendments. After entry of this Amendment, **claims 6 and 16-18 are pending in this application**. Consideration of the pending claims is requested.

#### *Elections/Restrictions*

Applicants note that the Office has acknowledged the election of Group I, claims 1-9 and 14, and that the Office has made the election final. Claims 10-13 and 15 are canceled as drawn to non-elected subject matter.

#### *Claim Objections*

Claims 1 and 6 are objected to for reciting “control plants”. Claim 1 has been canceled, thereby making its objection moot. Claim 6 has been amended to recite “. . . relative to a plant of the same species that does not comprise the plant transformation vector”. Applicants submit that by this amendment, the nature of the “control plants” is sufficiently formalized. Applicants respectfully request that the claim objections be withdrawn.

#### *Rejections under 35 U.S.C. §112, second paragraph*

Claims 1-9 and 14 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection, to the extent that it might still be applied to the amended claims.

The Office alleges that claims 1 and 6, and dependent claims 2-5, 7-9, and 14, are indefinite in reciting “an ortholog thereof” in relation to SEQ ID NO: 2, because the “use of the term ‘ortholog’ in the claim does not set forth the metes and bounds of the claimed invention” (Office action, page 4). Applicants respectfully disagree. However, solely to advance prosecution in this case, Applicants have removed reference to the term “ortholog” from independent claim 6, thereby making this rejection moot. Additionally, claims 1-5, 7-9, and 14 have been canceled, thereby making their rejection moot.

The Office also alleges that claim 6, and dependent claims 7 and 8 are indefinite in reciting the production of a plant with “an altered oil content phenotype” when the claim is directed to “a method of producing a high oil phenotype in a plant”. Applicants respectfully disagree. However, solely to advance prosecution in this case, Applicants have substituted the phrase “high-oil phenotype” for “an altered oil content phenotype”, in independent claim 6. It is believed that this term is sufficiently definite, and Applicants respectfully request that the rejection be withdrawn.

The Office also alleges that claim 9 is indefinite in reciting “direct progeny” and “indirect progeny”. Claim 9 has been canceled, thereby making this rejection moot.

In light of the above arguments and the amendments made herewith, Applicants respectfully request that these indefiniteness rejections be withdrawn.

*Rejections under 35 U.S.C. §112, first paragraph (enablement)*

Claims 1-9 and 14 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The claims are rejected because the specification allegedly “does not reasonably provide enablement for (i) a transgenic plant with increased oil content or a method of producing said transgenic plant comprising a nucleotide sequence that encodes an ortholog of SEQ ID NO: 2 and (ii) a transgenic plant with increased oil content or a method of making said transgenic plant comprising a nucleotide sequence which is complementary to a nucleotide sequence that encodes SEQ ID NO: 2” (Office action, page 6). Applicants respectfully traverse this rejection. In spite of this, and solely to advance prosecution

in this case, claims 6 is amended, as discussed below. It is believed that the amended claim at least is fully enabled by the specification. Additionally, claims 1-5, 7-9, and 14 have been canceled, thereby making their rejection moot.

Claim 6 has been amended to remove the reference to a complementary sequence element. At least this portion of the present rejection should be withdrawn.

Claim 6 has also been amended to be directed to a method of producing a high oil phenotype in a plant, the method comprising in part, “introducing into progenitor cells of the plant a plant transformation vector comprising . . . an amino acid sequence having at least 95% sequence identity to the amino acid sequence of SEQ ID NO: 2”.

The Office asserts that “[m]aking amino acid substitutions in SEQ ID NO: 2 is unpredictable . . . [because] the positions within the protein’s sequence where such amino acid changes can be made with a reasonable expectation of success (without altering protein function) are limited ” (Office action, page 10). The Office further asserts that “identification of related sequences that will encode enzymes having a particular catalytic activity is particularly problematic in the enzymes involved in modifying fatty acids” (Office action, page 11). But the question is not what effect a random mutation might have on the function of a protein sequence. Instead, it is whether the instant specification allows one of ordinary skill in the art to make and use a plant comprising a nucleotide sequence that (1) encodes a polypeptide sequence that has at least 95% sequence identity with SEQ ID NO: 2, and that (2) conveys a high oil phenotype on the plant. Applicants provide sufficient teachings in the specification, particularly in view of the level of skill of those in the art, to enable the scope of the invention as currently claimed.

The Federal Circuit has repeatedly stated that enablement is not precluded by the necessity for some experimentation, so long as the experimentation is not undue. *In re Wands* 8 USPQ2d 1400 (Fed. Cir. 1988). A considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance in which the experimentation should proceed. *Id.* The specification (see page 11, paragraph 0037 through page 12, paragraph 0038) clearly describes methods, which were well known to those of skill in

the art at the time the application was filed, for identifying and producing sequence variants, namely:

- (i) Sequence homology analysis, using BLAST and CLUSTAL programs, for example;
- (ii) Nucleic acid hybridization;
- (iii) Degenerate PCR and screening of a cDNA or genomic library;
- (iv) Antibody binding and expression libraries; and
- (v) Site directed mutagenesis.

Applicants point out that the requirement of at least 95% sequence identity to SEQ ID NO: 2 provides very predictable and defined structure for the sequences encompassed by the claims. This claimed percentage identity and the size of SEQ ID NO: 2 permits only up to 4 amino acid changes within the full-length 92 amino acid protein which can be readily produced, identified, and characterized by the above methods.

Significantly, the specification also teaches how any identified sequence of interest, such as SEQ ID NO: 2 and sequences having at least 95% sequence identity to SEQ ID NO: 2, can be used to generate plants with high oil phenotype and how to test for high oil content in transgenic plants transformed with such a sequence. For example, the identified sequence can be cloned into an over-expression vector which in turn can be used to generate transgenic plants that have a high oil phenotype compared to non-transgenic plants, as measured with NIR infrared spectroscopy (Example 5 at page 26, paragraph 0074 and 0075). Therefore, undue experimentation is not required to make and use a plant transformed with a nucleotide sequence that encodes a polypeptide sequence that has at least 95% sequence identity with SEQ ID NO: 2, and that conveys a high oil phenotype in the plant.

Thus, Applicants respectfully submit that in view of the teachings of the specification, and the knowledge of one of skill in the art at the time the application was filed, claim 6 is fully enabled. In light of the arguments presented above and the amendments of the claims, Applicants request that this rejection of claim 6 under 35 U.S.C. §112, first paragraph be withdrawn.

Applicants thank the Examiner for acknowledging that the specification provides enablement for a method of making a transgenic plant comprising a nucleic acid sequence that encodes an HIO32.2 polypeptide as set forth in SEQ ID NO: 2. Therefore, new claims 17 and 18 are enabled.

*Rejections under 35 U.S.C. §112, first paragraph (written description)*

Claims 1-9 and 14 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection. In spite of this, and solely to advance prosecution in this case, claim 6 is amended herewith and it is believed that the amendments clearly overcome the rejection, as discussed below. Claims 1-5, 7-9 and 14 have been canceled, thereby making their rejection under 35 U.S.C. §112, first paragraph moot.

The Office alleges that the claims are directed to a “broadly claimed genus [which] encompasses structures whose function is unrelated to the instantly claimed SEQ ID NO: 2” (Office action, page 16). The Office further alleges that “the only species described in the specification is SEQ ID NO: 1, which encodes SEQ ID NO: 2” and that “one of skill in the art would not recognize that Applicant was in possession of the necessary common attributes of the genus in view of the disclosed species” (*Id.*). Based on these statements, the Office concludes that the specification does not provide sufficient written descriptive support for the claims.

Applicants respectfully disagree that more than one sequence is necessary to establish adequate written description for a genus, at least for the following reasons.

As established in *Ex parte Parks*, “adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention. . . . Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed” *Ex parte Parks*, 30 USPQ2d 1234,

1236-37 (B.P.A.I. 1993) (emphasis added). Moreover, the MPEP at §2163 states that “[w]hat is conventional or well known to one of skill in the art need not be disclosed in detail. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384; 231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. *See, e.g. Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating “description need not be in *ipsis verbis* [i.e., “in the same words”] to be sufficient”).”

In the current instance, amended claim 6 recites “a plant transformation vector comprising . . . a nucleotide sequence that encodes a HIO32.2 polypeptide comprising the amino acid sequence having at least 95% sequence identity to the amino acid sequence of SEQ ID NO:2”. This language clearly and structurally describes the molecules that fall within the claimed subject matter. Moreover, the original disclosure clearly conveys that Applicants had possession of the claimed invention, and certainly of the concept of what is currently claimed. Applicants had possession of the polypeptide sequence in SEQ ID NO: 2; Applicants had also contemplated and provided explicit written description of polypeptides with at least 95% sequence identity to that sequence (for example, at page 9, paragraph 0032). Further, the specification describes how to determine which sequences have at least 95% sequence identity to SEQ ID NO: 2 (for example, at page 9, paragraph 0034). Methods are also provided for determining which residues are highly conserved (for example, at page 11, paragraph 0037); for making polypeptide variants (for example, at page 12, paragraph 0038; for the generation of transgenic plants (at page 13, paragraph 0043 to page 14, paragraph 0045); and for determining if a plant (particularly a transgenic plant) produces a high oil producing phenotype (for example, at page 7, paragraph 0025 and Example 1 on pages 17-18). Therefore, based on the teachings of the specification and the knowledge of one of skill in the art, a person of ordinary skill could envision sequences having at least 95% sequence identity to the sequence set forth in SEQ ID NO: 2. The pending claims are thus sufficiently described by the specification, and Applicants request that their rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

The Office is reminded that the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶ 1, “Written Description” Requirement 66 Fed. Reg. 1099, 1106 (2001). Satisfactory disclosure of a “representative number” depends on whether one of skill in the art would recognize that Applicants were in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. *Id.* Applicants respectfully submit that one of skill in the art reading the specification would recognize that Applicants had possession of the claimed invention in its full scope at the time the application was filed. Applicants respectfully request withdrawal of the rejection of claim 6, for lack of adequate written description.

*Rejections under 35 U.S.C. §102(b)*

Claims 1-9 and 14 are rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Alexandrov *et al.* Applicants respectfully traverse this rejection. In spite of this, and solely to advance prosecution in this case, claim 6 is amended, as discussed below. It is believed that the amended claim at least is free from the prior art. Additionally, claims 1-5, 7-9 and 14 have been canceled, thereby making their rejection under §102(b) moot.

The Office alleges that “Alexandrov *et al.* disclose a method of producing a transgenic plant cell comprising transformation of said plant cell with a plant transformation vector comprising an expression cassette which comprises a nucleic acid sequence encoding the polypeptide of SEQ ID NO: 65252 which has 100% sequence identity to instant SEQ ID NO: 2” (Office action, page 17). Although Alexandrov *et al.* does not describe making transgenic plants with a high oil phenotype, the Office alleges that “such a property would be inherent to the method of making a transgenic plant comprising overexpressing SEQ ID NO: 65252 protein.” The Office further alleges that this “method of making a transgenic plant is identical to the instantly claimed method of producing a high oil transgenic plant.” Applicants respectfully disagree, in as much as these assertions might apply to amended claim 6.

Alexandrov *et al.* do not disclose each and every step of present method claim 6. Nowhere do Alexandrov *et al.* disclose any **method** of producing a high oil phenotype in a plant by use of a nucleotide sequence comprising a heterologous constitutive promoter that is operatively linked to a nucleic acid that encodes a HIO32.2 polypeptide comprising an amino acid sequence having at least 95% sequence identity to the amino acid sequence of SEQ ID NO: 2. Alexandrov *et al.* also do not teach, suggest or disclose a **method** involving the overexpression of a HIO32.2 transcript to produce a high oil phenotype in a plant or “identifying a high oil phenotype in said transgenic plant by measuring relative oil content of the transgenic plant”, as presently claimed in claim 6. Thus, Alexandrov *et al.* does not anticipate the current claims because each and every element of the claimed invention is not disclosed in this reference.

Applicants further stress that Alexandrov *et al.* fail to anticipate the present disclosure because they do not disclose each and every element of the claimed invention, particularly not as arranged in the claim. The property of a high oil phenotype is a product of at least the components of the vector construct (including the nucleotide sequence that encodes the HIO32.2 polypeptide and the heterologous constitutive promoter) utilized by Applicants to transform the transgenic plant. Nowhere do Alexandrov *et al.* disclose the specific combination of a heterologous constitutive promoter and the nucleotide sequence that encodes the HIO32.2 polypeptide as presently arranged in Applicants’ claim 6. Therefore, the teachings of Alexandrov *et al.* are insufficient to establish anticipation, at least because each and every element of the claimed invention are not disclose as arranged in the presented claim.

Claims 1-9 and 14 are further rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Jako *et al* and by Zou *et al.* The Office notes that these rejections are “made because the recitation ‘ortholog’ in claims 1 and 6 read on any polypeptide that has the property of increasing seed oil content” (Office action, page 20). Applicants respectfully traverse these rejections. In spite of this, and solely to advance prosecution in this case, claim 6 is amended, as discussed above, to remove reference to the term “ortholog”. It is believed that the amended claim at least is thus free from Jako *et al.* and Zou *et al.* Additionally, claims 1-5, 7-9, and 14 have been canceled, thereby making their rejection under 35 U.S.C. §102(b) moot.

In view of the above arguments, and the amendments made herewith, Applicants request withdrawal of the rejections under 35 U.S.C. §102(b).

### **Conclusion**

Based on the foregoing amendments and arguments, the claims are in condition for allowance and notification to this effect is requested. If for any reason the Examiner believes that a telephone conference would expedite allowance of the claims, please telephone the undersigned at the telephone number listed below.

Respectfully submitted,

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